

### **REMARKS**

Claims 2-6, 10-11, and 15-29 are now pending in the application. Claim 14 has been cancelled without prejudice or disclaimer of the subject matter contained therein and new claims 28-29 have been added herein. The amendments to the claims contained herein are of equivalent scope as originally filed and, thus, are not a narrowing amendment. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments and remarks contained herein.

### **NEW MATTER OBJECTION/REJECTION**

The Examiner objects to the amendment filed on July 7, 2003 asserting that it introduces new matter into the disclosure. The Examiner specifically identified "a focused light source" as not being supported by the original disclosure and requires the Applicant to cancel the new matter.

The Examiner also rejects claims 2-6, 10, 11 and 20-26 under 35 U.S.C. § 112, first paragraph in as much as the claims contain subject matter, which was not described in the specification in such a way to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Again, the Examiner noted that the originally filed disclosure was silent with regard to "a focused light source."

In the above-referenced amendment, Applicant distinguished the present invention which employs a single light source to fix a patient's eye during surgery from the array of light sources disclosed in the prior art. Applicant was not intending to claim a light source which, through the use of some means such as a lens, converged at a point in space.

Since it appears that the Examiner has adopted an interpretation of the term “focused light source” as light source which converges at a point in space, Applicant amends the claims to substitute the term “a single light source” for the term “focused light source”, thereby eliminating the term objected to by the Examiner. As such, Applicant does not limit the scope of the claim but rather particularly points out and distinctly claims the subject matter which is regarded as the invention, namely a single light source as opposed to the multiple or array of light sources taught by the cited references. The application as originally filed including the detailed description and drawings clearly support the invention as presently claimed. Accordingly, the Examiner is respectfully requested to withdraw his objection to the amendment and his rejection of claims 2-6, 10, 11 and 20-26.

**REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH**

Claims 2-6, 14-19, and 20 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is respectfully traversed.

Specifically, the Examiner rejected claim 20 stating that “the exact meaning of the term ‘to define a target point, wherein said light source directs a receptor at said target’ point is unclear.” Applicant submits that the specification, and in particular paragraphs 0011 and 0025 clarify the meaning of the above-referenced phrase. Nevertheless, Applicant has further amended claim 20 to recite “a single light source mounted on said eye shield to define a target point which fixates said eye at said target point. . .”

Claim 19 was rejected on the basis that the term “a disposable fixation device” was unclear. Applicant has canceled claim 19 herein, thereby rendering this rejection moot. The Examiner’s attention is directed to new claim 29 which depends from the independent method claim and further recites disposing of the eye shield.

The Examiner rejected claim 14 as incomplete for its failure to recite a “surgical step.” Applicant respectfully traverse the Examiner’s rejection in that a surgical procedure should not require an operative procedure *per se*. Applicant has canceled claim 14, thereby rendering the Examiner’s rejection moot. The Examiner’s attention is directed to new claim 28 which recites a method for aligning a conjugate for topical anesthesia eye surgery. Accordingly, a surgical procedure, *per se*, is no longer being claimed. Rather the claim is directed to a method for aligning an eye for topical anesthesia eye surgery. The Examiner should note that claim 27 further defines the procedure as including an operation step - - i.e. a cataracts procedure.

In view of the foregoing amendments and remarks, Applicant respectfully requests that the Examiner reconsider and withdraw the rejections under 35 U.S.C. § 112, second paragraph.

**PRIOR ART REJECTION UNDER 35 U.S.C. § 102 AND 35 U.S.C. § 103(a)**

**Method Claims**

Claims 14, 16, 17 and 19 stand rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Marshall (U.S. Patent No. 5,293,532). Claims 14, 15, and 18 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Marshall in combination with Chen et al. (U.S. Patent No. 5,884,340). Claims 14, and 27 stand

rejected under 35 U.S.C. § 103(a) as being unpatentable over Marshall in combination with Swinger et al. The rejection of these method claims is respectfully traversed.

The Examiner had previously indicated claims 14-19 were directed to allowable subject matter, but withdrew this indication in view of a newly-discovered reference to Marshall. Applicant agrees that the Marshall reference teaches the concept of positioning a subject or conjugate eye by fixating the occluded or fellow eye on an illuminated object. However, Applicant submits that the Marshall reference failed to disclose the specific method recited in claim 28 and the claims which depend therefrom. In particular, the Marshall reference fails to teach the process of “locating an eye shield having a relieved portion with a single light source over the fellow eye . . . [and] adhesively securing a rim portion of the eye shield to a face of the patient . . .” Rather, Marshall discloses an eye piece (such as 222) which includes multiple light sources 58. Moreover, the device 210 is attached to a band 212 for wearing about the head of the patient 38. The device 210 further includes Bellows 228 for adjusting to the facial contours of the eyes of the patient. See generally Marshall, Column 5, lines 58-68. Thus, Marshall fails to disclose a device having a relief portion with a single light source.

The Examiner notes that Marshall fails to disclose adhesively securing a portion of the eye shield to the face of the patient. The Examiner references the teaching of Chen *et al.* as demonstrating that it would be been obvious to employ adhesive tape in place of the straps of Marshall. Initially, it should be noted that the Chen *et al.* reference is directed to a clothing article for scantily covering select portions of the human body, such as articles which may be purchased at an adult bookstore or erotic clothing shop.

As such, Applicant submits that the Chen *et al.* reference is a non-analogous to the eye fixation device for anesthesia eye surgery in the present application.

Moreover, Applicant submits that Chen *et al.* does not provide such a teaching. Instead, Chen *et al.* teaches the substitution of buttons, adhesive, adhesive tapes, sewing, clips, magnet, buckles, or the like in place of the hook and loop fastener 216 disposed on straps 212. See Chen *et al.*, column 2, lines 52-55 and column 4, lines 24-26. The use of a strap or head band is inferior to the securing method of the present invention in that the eye shield could move during the surgical procedure, thereby undesirably realigning the position of the eye. By adhesively securing the eye shield to the face of the patient, the likelihood of unwanted movement of the eye shield is significantly reduced.

#### **APPARATUS CLAIMS**

Claims 2-6, 10, 11 and 20-25 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Marshall in combination with Unger et al. (U.S. Patent No. 6,164,789) and Chen et al. These rejection are respectfully traversed.

As discussed above, Marshall teaches an eye piece having an array (i.e., multiple) light sources disposed therein for visually stimulating and facilitating repositioning of the eye. Specifically, Marshall notes that “using an array of light sources allows the practitioner to reposition the illuminated source relative to the eye without physically moving a wand or otherwise engaging in trial-and-error techniques requiring interruption of the examination or procedure and consequent loss of concentration.” Marshall, Column 2, lines 59-64. Thus, Marshall fails to teach the use of an eye shield with a single light source, and further teaches away from such an

invention. The Examiner further relies on Chen *et al.* to teach substitution of an adhesive for attaching the eye shield to the skin rather than the straps. However, as noted above, Applicant submits that Chen *et al.* does not teach the substitution of adhesively securing the shield to the skin, but rather teaches the substitution of adhesive tape for the hook and loop fasteners on the straps. As discussed above, such a substitution does not render the present invention obvious nor provide a suitable alternate means for securing the eye shield to the patient.

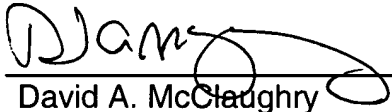
Furthermore, Applicant submits that the Examiner has failed to present a *prima facie* case that the prior art discloses an eye shield having a relieved portion and a rim portion extending from the relieved portion that receives an adhesive as needed in claim 20, and further wherein the rim has a tear dropped shaped as recited in claim 11 . Likewise, the Examiner has failed to present a *prima facie* case of obviousness that the prior art teaches or suggests an eye shield having a dome and a rim extending from the dome receiving an adhesive as recited in claim 22. Likewise, the Examiner has failed to show that the prior art teaches or suggests an eye shield as recited in claim 21 wherein the rim comprises a substantially planar portion extending laterally from the dome or wherein the dome is a segment of a sphere. In view of the foregoing deficiencies, Applicant respectfully requests that the Examiner reconsider and withdraw his rejection under Section 103 of the apparatus claims in the present application.

**CONCLUSION**

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600.

Respectfully submitted,

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